

	9 2003 🖏		Application S	Serial Number	09/545	09/545,162					
JUN	3 mm (2)		Filing Date		April '	April 7, 2000					
TE TRAI	TAR RESERVE		First Named	Inventor	Lapida	Lapidus 1634					
HA	TRANSMITTA	T	Group Art U	nit	1634						
Ì			Examiner Na	me	Einsm	ann, J.					
	FORM		Attorney Doo	cket No.	EXT-0	026					
			Patent No.		Not ap	pplicable					
			Issue Date		Not ap	pplicable					
		EN	CLOSURES (ch	eck all that apply)	<del></del>						
□ F	ee Transmittal Form		Copy of Notice	to File Missing		Notice of Appeal to Board					
	Check Attached		Parts of Applic	ation		of Patent Appeals and Interferences					
	Copy of Fee Transmittal Form	Formal Drawin	g(s)		Appeal Brief (in triplicate)						
	Amendment/Response with Declaration attachment Preliminary	Request For Co Examination (F Transmittal			Status Inquiry						
	After Final				$\boxtimes$	Return Receipt Postcard					
	☐ Affidavits/declaration(s) ☐ Letter to Official ☐ Draftsperson		Power of Attor (Revocation of		×	Certificate of First Class Mailing under 37 C.F.R. 1.8					
	including Drawings [Total Sheets]		Terminal Discl	aimer		Certificate of Facsimile Transmission under 37 C.F.R. 1.8					
	Petition for Extension of Time			aration and Power Utility or Design tion		Additional Enclosure(s) (please identify below)					
⊠	Information Disclosure Statement		Small Entity St	tatement							
	<ul> <li>✓ Form PTO-1449</li> <li>✓ Copies of IDS</li> <li>Citations A1-A117,</li> <li>B1-B111, C1-C177</li> </ul>		CD(s) for large program	CD(s) for large table or computer program							
	Certified Copy of Priority Document(s)		Amendment A								
	Copy of Sequence Listing submission		Request for Ce Correction	ertificate of							
	☐ Paper Copy/CD ☐ Copy of Computer Readable Copy		Certificate duplicate)	of Correction (in							
	Statement verifying identity of above										
COR	RESPONDENCE ADDRESS	<u> </u>		SIGNATURE BL	OCK						
		dministrato	or			Respectfully submitted,					
		-7000	Date: June 5, 20 Reg. No. 51,752 Tel. No.: (617) 310 Fax No.: (617) 248	-8423	Jennifer E. Grant Attorney for Applicants Testa, Hurwitz & Thibeault, LLP High Street Tower 125 High Street Boston, MA 02110						



PATENT Attorney Docket No. EXT-026

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):

Lapidus et al.

**SERIAL NO.:** 

09/545,162

**GROUP NO.:** 

1634

FILING DATE:

April 7, 2000

**EXAMINER:** 

Einsmann, J.

TITLE:

Methods For Detecting Nucleic Acids Indicative of Cancer

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

### INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

In addition, Applicants notify the Examiner of the following U.S. patent applications: U.S. Serial No. 09/514,865, filed February 28, 2000; U.S. Serial No. 09/455,950, filed December 7, 1999; U.S. Serial No. 10/149,464, filed June 7, 2002; and U.S. Serial No. 09/724,274, filed November 28, 2000. Furthermore, Applicants notify the Examiner that U.S. Patent No. 6,084,091 (A111) is the English language counterpart of Foreign Patent Document Nos. 195 30 132C2 (B47), 195 30 132A1 (B110) and WO 97/07239 (B58); U.S. Patent No. 6,150,100 (A109) is the English language counterpart of Foreign Patent Document No. 197 12 332A1 (B48); U.S. Patent No. 6,448,002B1(A110) is the English language counterpart of Foreign Patent Document No. WO 98/08971 (B61); and an English language abstract for Foreign Patent Document No. 197 36 691A1 (B49) is contained in related Foreign Patent Document No. WO 99/10528 (B111).

#### **REMARKS**

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

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(1) within three (3) months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. 1.491 in an

Information Disclosure Statement Serial No. 09/545,162 Page 2 of 2

		international application, or before the mailing of the first Office action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. 1.114; or							
	(2)	after the period defined in (1) but before the mailing date of a final action or a n of allowance under 37 C.F.R. 1.311, and							
		the requisite Statement is below	v, OR						
		the requisite fee under 37 C.F.I	R. 1.17(p), namely \$180.00, is included herein, or						
	(3)	after the mailing date of a final of the issue fee, AND	action or notice of allowance but before the payment						
		the requisite Statement is below	below, AND						
		the requisite petition fee under	tion fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.						
			atents and publications listed on the attached Form n, be made of record in this application.						
		F	Respectfully submitted,						
Date: June <u>5</u> , 2003 Reg. No. 51,752			Jennifer E. Grant () Attorney for Applicant(s) Testa, Hurwitz, & Thibeault, LLP						
Tel. No.: (6 Fax No.: (6		0-8423 F 8-7100 1	High Street Tower 125 High Street Boston, Massachusetts 02110						





PATENT Attorney Docket No. EXT-026 (2457/23)

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S):

Lapidus et al.

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09/545,162

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1634

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**EXAMINER:** 

Einsmann, J.

TITLE:

Methods For Detecting Nucleic Acids Indicative of Cancer

### CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Arlington, VA 22202-1450 on this 5 th day of June 2003.

Thomas F. Hellenthal

Commissioner for Patents P.O. Box 1450 Arlington, VA 22202-1450

Sir:

### Submitted herewith is/are:

- 1. Transmittal Form (1 page);
- 2. Information Disclosure Statement (2 pages);
- 3. Form PTO 1449 (22 pages);
- Copies of references A1-A117, B1-B111, C1-C177
   (A1-A117 and B1-B27 in Box 1; B28-B111 in Box 2; C1-C177 in Box 3);
- 5. Return Receipt Postcard.

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INFORMATION DISCLOSURE STATEMENT

JUN 0 9 2003 à

ATTORNEY DOCKET NO.: EXT-026

APPLICANT(S): Lapidus et al.

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GROUP: 1634

### U.S. PATENT DOCUMENTS

EXAM.		DOCUMENT				SUB	FILING DATE IF
NIT.		NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	Al	4,333,734	6/8/82	Fleisher			10/8/80
	A2	4,535,058	8/13/85	Weinberg et al.			10/1/82
	A3	4,683,195	7/28/87	Mullis et al.			2/7/86
	A4	4,786,718	11/22/88	Weinberg et al.			8/8/85
	A5	4,857,300	8/15/89	Maksem			7/27/87
	A6	4,871,838	10/3/89	Bos et al.			7/23/85
	A7	4,981,783	1/1/91	Augenlicht			4/16/86
	A8	4,982,615	1/8/91	Sultan et al.			4/18/89
	A9	5,087,617	2/11/92	Smith			2/15/89
	A10	5,126,239	6/30/92	Livak et al.			3/14/90
	A11	5,137,806	8/11/92	LeMaistre et al.			12/11/89
	A12	5,196,167	3/23/93	Guadagno et al.			5/9/91
	A13	5,248,671	9/28/93	Smith			12/9/91
	A14	5,272,057	12/21/93	Smulson et al.			12/21/93
	A15	5,302,509	4/12/94	Cheeseman			2/27/91
	A16	5,330,892	7/19/94	Vogelstein et al.			3/13/91
	A17	5,348,855	9/20/94	Dattagupta et al.			10/4/91
	A18	5,352,775	10/4/94	Albertsen et al.			8/8/91
-	A19	5,362,623	11/8/94	Vogelstein et al.			3/31/92
	A20	5,369,004	11/29/94	Polymeropoulos et al.			7/31/92
	A21	5,378,602	1/3/95	Polymeropoulos et al.			11/27/91
	A22	5,380,645	1/10/95	Vogelstein			3/16/89
	A23	5,380,647	1/10/95	Bahar			4/26/93
<u>-</u>	A24	5,382,510	1/17/95	Levine et al.			7/10/92
	A25	5,409,586	4/25/95	Kamahori et al.			8/24/93

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EXAM.		DOCUMENT				SUB	FILING DATE IF
IŃIT.		NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	A26	5,458,761	10/17/95	Kamahori et al.			1/27/95
	A27	5,466,576	11/14/95	Schulz et al.			7/2/93
	A28	5,468,610	11/21/95	Polymeropoulos et al.			6/9/93
	A29	5,468,613	11/21/95	Erlich et al.			3/9/90
	A30	5,489,508	2/6/96	West et al.			3/24/93
	A31	5,492,808	2/20/96	de la Chapelle et al.			5/5/93
	A32	5,496,470	3/5/96	Lenhart			5/27/94
	A33	5,508,164	4/16/96	Kausch et al.			10/29/93
	A34	5,512,441	4/30/96	Ronal			11/15/94
	A35	5,514,547	5/7/96	Balazs et al.			2/4/94
	A36	5,527,676	6/18/96	Vogelstein et al.			3/22/93
	A37	5,532,108	7/2/96	Vogelstein			4/14/94
	A38	5,580,729	12/3/96	Vogelstein			6/24/94
	A39	5,589,335	12/31/96	Kearney et al.			8/11/94
	A40	5,670,325	9/23/97	Lapidus et al.			8/14/96
	A41	5,709,998	1/20/98	Kinzler et al.			12/15/93
	A42	5,710,028	1/20/98	Eyal et al.			10/4/94
	A43	5,741,650	4/21/98	Lapidus et al.			4/21/98
	A44	5,759,777	6/2/98	Kearney et al.			6/2/98
	A45	5,830,665	11/3/98	Shuber et al.			3/3/97
	A46	5,928,870	7/27/99	Lapidus et al.			6/16/97
	A47	3,413,464	11/26/68	Kamentsky			04/29/65
	A48	4,101,279	7/18/78	Aslam			4/6/77
	A49	4,309,782	1/12/82	Paulin			9/11/80
	A50	4,358,535	11/9/82	Falkow et al.			12/8/90

	EXAMINER	DATE CONSIDERED
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INFORMATION DISCLOSURE STATEMENT

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EXAM.		DECEMENT				SUB	FILING DATE IF	
INIT.	DOCESTA		DATE	NAME	CLASS	CLASS	APPROPRIATE	
	A51	4,445,235	5/1/84	Slover et al.			9/13/82	
	A52	4,578,358	3/25/86	Oksman et al.			5/3/83	
	A53	4,683,202	7/28/87	Mullis			10/25/85	
	A54	4,705,050	11/10/87	Markham			10/2/85	
	A55	4,735,905	4/5/88	Parker			8/15/86	
	A56	4,935,342	6/19/90	Seligson et al.			12/1/86	
	A57	5,149,506	9/22/92	Skiba et al.			8/9/91	
	A58	5,200,314	4/6/93	Urdea			3/23/90	
	A59	5,331,973	7/26/94	Fiedler et al.			3/15/93	
	A60	5,416,025	5/16/95	Krepinsky, et al.			8/31/94	
	A61	5,463,782	11/7/95	Carlson et al.			11/21/94	
	A62	5,482,834	1/9/96	Gillespie			1/19/93	
	A63	5,506,105	4/9/96	Haydock			3/22/94	
	A64	5,538,851	7/23/96	Fach et al.			12/22/93	
	A65	5,559,014	9/24/96	Estes et al.			6/7/95	
	A66	5,599,662	2/4/97	Respess			2/17/95	
	A67	5,612,473	3/18/97	Wu et al.			1/16/96	
	A68	5,635,352	6/03/97	Urdea et al.			4/26/95	
	A69	5,641,628	6/24/97	Bianchi			11/14/94	
	A70	5,645,995	7/8/97	Kieback			4/12/96	
	A71	5,688,643	11/18/97	Oka et al.			2/27/95	
	A72	5,846,710	12/8/98	Bajaj			8/6/93	
	A73	5,856,104	1/5/99	Chee et al.			3/7/97	
	A74	5,882,865	03/16/99	Vogelstein et al.			1/10/97	
	A75	5,888,778	3/30/99	Shuber	<del>-    </del>		6/16/97	

EXAMINER	DATE CONSIDERED
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# U.S. PATENT DOCUMENTS

EXAM.		DOCUMENT				SUB	FILING DATE IF
INIT.		NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	A76	5,910,407	6/8/99	Vogelstein et al.			8/26/94
<del></del>	A77	5,916,744	6/29/99	Taylor			3/14/94
	A78	5,942,396	8/24/99	Shiff et al.			8/19/97
	A79	5,952,178	9/14/99	Lapidus et al.			4/13/98
	A80	5,976,800	11/2/99	Lau et al.			6/27/97
	A81	6,020,137	2/1/00	Lapidus et al.			11/23/98
	A82	6,037,465	3/14/00	Hillebrand et al.			12/16/96
	A83	6,100,029	8/8/00	Lapidus et al.			12/4/97
	A84	6,143,529	11/7/00	Lapidus et al.			3/26/99
	A85	6,146,828	11/14/00	Lapidus			7/3/98
-	A86	6,177,251B1	01/23/01	Vogelstein et al.			6/8/99
	A87	6,203,993 B1	3/20/01	Shuber et al.			4/4/00
<del></del>	A88	6,214,187B1	4/10/01	Hammond et al.			6/18/99
	A89	6,214,558B1	04/10/01	Shuber et al.			7/27/00
	A90	6,238,927B1	5/29/01	Abrams et al.			10/4/99
	A91	6,251,660 B1	6/26/01	Muir et al.	<del></del>		11/25/98
	A92	6,268,136B1	7/31/01	Shuber et al.	-		11/23/98
	A93	6,280,947 B1	8/28/01	Shuber et al.			8/11/99
	A94	6,300,077 B1	10/9/01	Shuber et al.			4/4/00
	A95	6,303,304 B1	10/16/01	Shuber et al.			2/2/99
	A96	6,351,857 B2	3/5/02	Slaon, III et al.			3/13/01
	A97	6,406,857 B1	6/18/02	Shuber et al.			5/21/01
	A98	6,415,455 B1	7/9/02	Slaon, III et al.			12/17/01
	A99	6,428,964 B1	8/6/02	Shuber			3/15/01
	A100	6,475,738 B2	11/5/02	Shuber et al.			6/18/01

EXAMINER	DATE CONSIDERED

INFORMATION DISCLOSURE STATEMENT

JUN 0 9 2003

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INIT.		NUMBER	DATE	NAME	CLASS	CLASS	APPROPRIATE
	A101	6,482,595 B2	11/19/02	Shuber et al.			8/27/01
	A102	2001/0018180A1	8/30/01	Shuber et al.			1/10/01
	A103	2002/0025525A1	2/28/02	Shuber			5/30/01
	A104	2002/0110810A1	8/15/02	Shuber			1/5/01
	A105	2002/0119469A1	8/29/02	Shuber et al.		1	10/5/01
	A106	2002/0119472A1	8/29/02	Lapidus et al.			10/15/01
	A107	2002/0132251A1	9/19/02	Shuber			11/20/01
	A108	2002/0164631A1	11/7/02	Shuber et al.			3/25/02
	A109	6,150,100	11/21/00	Ruschoff et al.			3/25/98
	A110	6,448,002B1	9/10/02	Hillebrand et al.		ļ	8//26/97
	A111	6,084,091	7/4/00	Muller et al.			8/14/96
	A112	6,503,718 B2	1/7/03	Shuber et al.			1/10/01
	A113	6,551,777	4/22/03	Shuber et al.			1/24/00
	A114	6,498,012	12/24/02	Laken			6/18/01
	A115	2003/0087258A1	5/8/03	Shuber			4/11/02
	A116	2003/0044780A1	3/6/03	Lapidus et al.			11/23/99
	A117	2003/0049659A1	3/13/03	Lapidus et al.			5/29/02

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INFORMATION TO SELOTURE STATEMENT

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EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	BI	0 284 362 A2	9/28/88	EP			3/23/88		Y
	B2	0 337 498 A2	10/18/89	EP			4/17/89		Y
	В3	WO 90/09455	8/23/90	PCT			2/13/90		Y
-	B4	0 390 323 A2	10/3/90	EP			2/20/90		Y
	B5	0 390 323 A3	10/3/90	EP			2/20/90		Y
	В6	0 407 789 A1	1/16/91	EP			6/22/90		Y
	В7	0 407 789 B1	1/16/91	EP			6/22/90		Y
	B8	WO 92/13103	8/6/92	PCT			1/16/92		Y
	B9	WO 92/16657	10/1/92	PCT			3/12/92		Y
	B10	WO 93/18186	9/16/93	PCT			3/1/93		Y
	B11	WO 93/20233	10/14/93	PCT			3/22/93		Y
	B12	WO 94/01447	1/20/94	PCT			7/1/93		Y
	B13	WO 94/09161	4/28/94	PCT			10/20/93		Y
	B14	WO 94/10575	5/11/94	PCT			10/29/93		Y
	B15	WO 94/11383	5/26/94	PCT			11/8/93		Y
	B16	0 608 004 A2	7/27/94	EP			8/11/87		Y
	B17	A-11325/95	10/5/94	AU					Y
	B18	0 259 031 B1	11/9/94	EP			8/11/87		Y
	B19	WO 95/07361	3/16/95	PCT			9/9/94	Abstract in English	N
	B20	WO 95/09928	4/13/95	PCT			9/26/94		Y
	B21	WO 95/09929	4/13/95	PCT			9/26/94		Y
	B22	0 648 845 A2	4/19/95	EP			7/2/94		Y
	B23	WO 95/13397	5/18/95	PCT			11/10/94		Y
T	B24	WO 95/15400	6/8/95	PCT			12/5/94		Y

EXAMINER	DATE CONSIDERED
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EXAM. INIT.		DOCUME BADEN NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B25	WO 95/16792	6/22/95	PCT			12/13/94	Abstract in English	N
	B26	WO 95/18818	7/13/95	PCT	· · · · · · · · · · · · · · · · · · ·		1/3/95		Y
	B27	WO 95/19448	7/20/95	PCT			1/13/95		Y
·/	B28	0 664 339 A1	7/26/95	EP			7/7/94		Y
	B29	WO 95/25813	9/28/95	PCT			3/17/95		Y
	B30	WO 95/31728	11/23/95	PCT			5/15/95		Y
	B31	WO 96/01907	1/25/96	PCT			7/10/95		Y
V	B32	WO 96/06951	3/7/96	PCT			8/31/95		Y
1	B33	WO 96/08514	3/21/96	PCT			9/12/95		Y
-	B34	WO 96/12821	5/2/96	PCT			12/19/95		Y
Ĺ	B35	WO 96/13611	5/9/96	PCT			10/27/95		Y
	B36	WO 96/30545	10/3/96	PCT			2/14/96		Y
	B37	WO 97/09449	3/13/97	PCT			9/2/96		Y
	B38	WO 97/09600	3/13/97	PCT			9/5/96		Y
	B39	WO 97/23651	7/3/97	PCT			12/20/96		Y
	B40	WO 97/25442	7/17/97	PCT			1/9/97		Y
	B41	WO 98/38338	9/3/98	PCT			2/27/98		Y
Mandate States	B42	WO 98/58081	12/23/98	PCT			6/4/98		Y
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	B44	0 270 017A3	6/8/88	EP			11/27/87		Y
	B45	0 284 362 A3	9/28/88	EP			3/23/88		Y
	B46	0 391 565 B1	10/10/90	EP			3/19/90		Y
	B47	195 30 132C2	2/20/97	DE			8/16/95	A111 is English counterpart	N

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ATTORNEY DOCKET NO.: EXT-026

APPLICANT(S): Lapidus et al.

SERIAL NO.: 09/545,162

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FOREIGN PATENT DOCUMEN
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EXAM. INIT.		DOCUMENTARY NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B48	197 12 332A1	10/1/98	DE			3/25/97	A109 is English counterpart	N
	B49	197 36 691A1	2/25/99	DE			8/22/97	B111 has English abstract	N
	B50	2,327,497A	1/27/99	GB			7/15/98		Y
	B51	WO 93/20235	10/14/93	PCT			3/31/93		Y
	B52	WO 94/00603	1/6/94	PCT			6/28/93		Y
<del></del>	B53	WO 94/01447	1/20/94	PCT			7/1/93		Y
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	B55	WO 95/12606	5/11/95	PCT			11/5/93		Y
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	B57	WO 96/29430A	9/26/96	PCT			3/13/96		Y
	B58	WO 97/07239	2/27/97	PCT			8/14/96	A111 is English counterpart	N
	B59	WO 97/19191A	5/29/97	PCT			11/15/96		Y
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<del> </del>	B61	WO 98/08971	3/5/98	PCT			8/26/97	A110 is English counterpart	N
	B62	WO 98/39478	9/11/98	PCT			3/2/98		Y
	B63	WO 98/58084	12/23/98	PCT			6/16/98		Y
	B64	WO 99/07894	2/18/99	PCT			8/5/98		Y
	B65	WO 99/07895	2/18/99	PCT			4/8/98		Y
	B66	WO 99/20798	4/29/99	PCT			10/22/98		Y
_	B67	WO 99/26724	6/3/99	PCT			11/25/98		Y

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INFORMATION DISCLOSURE STATEMENT

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# FOREIGN PATENT DOCUMENTS

EXAM. INIT.		NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B68	WO 99/28507	6/10/99	PCT			12/3/98		Y
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	B70	WO 99/53316	10/21/99	PCT			4/13/99		Y
	B71	WO 99/55912	11/4/99	PCT			4/23/99	_	Y
<del></del>	B72	WO 99/66077	12/23/99	PCT			6/16/99		Y
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	B75	WO 00/09751	2/24/00	PCT			8/10/99		Y
	B76	WO 00/11215	3/2/00	PCT			8/10/99		Y
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	B78	WO 00/31303	6/2/00	PCT			11/22/99		Y
	B79	WO 00/31305	6/2/00	PCT			11/23/99		Y
	B80	WO 00/32820	6/8/00	PCT			11/23/99		Y
	B81	WO 00/50640	8/31/00	PCT			1/24/00		Y
	B82	WO 00/50870	8/31/00	PCT			2/25/00		Y
	B83	WO 00/58514A3	10/5/00	PCT			3/24/00		Y
	B84	WO 00/60118	10/12/00	PCT			3/31/00		Y
	B85	WO 00/61808A3	10/19/00	PCT			4/7/00		Y
	B86	WO 00/66005	11/9/00	PCT			4/26/00		Y
	B87	WO 00/70096	11/23/00	PCT			5/18/00		Y
	B88	WO 00/70096A3	11/23/00	PCT			5/18/00		Y
	B89	WO 01/18252A2	3/15/01	PCT			9/8/00		Y
	B90	WO 01/42502A2	6/14/01	PCT			9/8/00		Y
	B91	WO 01/42503A2	6/14/01	PCT			11/28/00		Y
	B92	WO 01/42781A2	6/14/01	PCT			12/7/00		Y

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### INFORMATION DISCLOSURE STATEMENT

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•	B93	WO01/64950A2	9/7/01	PCT			2/27/01		Y
	B94	WO01/64950A3	9/7/01	PCT			2/27/01		Y
	B95	WO01/11083A2	2/15/01	PCT			8/9/00		Y
	B96	WO01/11083A3	2/15/01	PCT			8/9/00		Y
	B97	WO02/055740A2	7/18/02	PCT			1/10/02		Y
	B98	WO02/059379A2	8/1/02	PCT			1/4/02		Y
	B99	WO02/074995A1	9/26/02	PCT			3/15/02		Y
	B100	WO02/092858A2	11/21/02	PCT			2/28/02		Y
	B101	AU199942333A1	9/30/99	AU			7/28/99		Y
	B102	711754	7/17/97	AU			12/20/96		Y
	B103	704696	8/22/97	AU			12/20/96		Y
	B104	720489	9/30/99	AU			7/28/99		Y
	B105	744746	1/4/99	AU			6/16/98		Y
	B106	745862	9/22/98	AU			3/2/98		Y
	B107	2,211,702	5/25/99	CA			12/20/96		Y
	B108	2,228,769	2/27/97	CA			8/14/96	-	Y
	B109	3325270	9/17/02	JP			12/20/96	Abstract in English	N
	B110	195 30 132A1	2/20/97	DE			8/16/95	A111 is English counterpart	N
	B111	WO 99/10528	3/4/99	РСТ			8/22/97	Abstract in English	N

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	70M -		FILING DATE: April 7, 2000 GROUP: 1634		
- A	TE TR	OTHER ART, JOURN	NAL ARTICLES, ETC.		
EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Tit	tle, Date, Relevant Pages, Place of Publication)		
	C1	Aaltonen et al. (1994) "Replication Errors in I Colorectal Cancer Patients" <u>Cancer Research</u> :	Benign and Malignant Tumors from Hereditary Nonpolyposis 54:1645-1648.		
	C2	Aaltonen et al. (1998) "Incidence of Hereditar Molecular Screening for the Disease" The New	et al. (1998) "Incidence of Hereditary Nonpolyposis Colorectal Cancer and the Feasibility of Screening for the Disease" The New England Journal of Medicine 338:1481-1487.		
	C3		subel et al., (1995), Short Protocols in Molecular Biology, 3d ed., pp. 2-3 -2-12, 3-30 -3-33.		
	C4		cer Following Colonoscopic Polypectomy" Tumori 85:157-162		
	C5		kin et al., (1995), "On the Mechanism of the Modular Primer Effect" Nucleic Acids Pesserah, Vol. 22		
	C6 Blum H.E., (1995) "Colorectal Cancer: Future Population Screening for Early Colorectal Cancer" Europ Journal of Cancer, Vol. 31A, pp. 1369-1372.				
C7 Bos et al., (May 28, 1987) "Prevalence of ras Gene Mutations in Human Colorectal Cance Vol. 327, pp. 293-297.			Gene Mutations in Human Colorectal Cancers," Nature,		
	C8	Caldas et al., (July 1, 1994) "Detection of K-ras Mutations in the Stool of Patients with Pancreatic Adenocarcinoma and Pancreatic Ductal Hyperplasia" Cancer Research, Vol. 54, pp. 3568-3573.			
	C9	Capozzi et al. (1999) "Evaluation of the Replic	cation Error Phenotype in Relation to Molecular and Early Onset Colorectal Cancer" <u>European Journal of Cancer</u>		
C10 Cave et al., (1994) "Reliability of PCR Directly from Stool Samples: Usefulness of an BioTechniques, Vol. 16, No. 5, pp. 809-810.		y from Stool Samples: Usefulness of an Internal Standard,"			
	C11	Chapelle (1999) " Testing Tumors for Microsat 7:407-408.	tellite Instability" European Journal of Human Genetics		
C12 Charlesworth et al., (September 15, 1994) "The Evolutionary Dynamics of Repetitive DNA in Nature, Vol. 371, pp. 215-220.  C13 Chen et al. (1997) "Microsatellite Instability in Sporadic-Colon-Cancer Patients With and Wit Metastases" International Journal of Cancer 74:470-474.  C14 Coll et al., (October 1989) "Evaluation of a Rapid Method of Extracting DNA from Stool Sam Hybridization Assays," Journal of Clinical Microbiology, Vol. 27, No. 10, pp. 2245-2248.  C15 Coughlin et al. (1999) "Public Health Perspectives on Testing for Colorectal Cancer Susceptib American Journal of Preventive Medicine 16:99-104.		Evolutionary Dynamics of Repetitive DNA in Eukaryotes,"			
		Sporadic-Colon-Cancer Patients With and Without Liver 470-474.			
		pid Method of Extracting DNA from Stool Samples for Use in robiology, Vol. 27, No. 10, pp. 2245-2248.			
		ves on Testing for Colorectal Cancer Susceptibility Comes			
	C16	Cunningham C. and M.G. Dunlop, (1996) "Mol British Journal of Surgery, Vol. 83, pp. 321-329	lecular Genetic Basis of Colorectal Cancer Susceptibility,"		

**EXAMINER** 

DATE CONSIDERED

FORM PTO - 1449			ATTORNEY DOCKET NO.: EXT-026		
INFORMATION OF STATEMENT			APPLICANT(S): Lapidus et al.		
		O B 2002 B	SERIAL NO.: 09/545,162		
	_ \3		FILING DATE: April 7, 2000 GROUP: 1634		
	K	OTHER ART, JOURN	NAL ARTICLES, ETC.		
EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Ti			
	C17	Deng et al., (December 20, 1996) "Loss of He Science, Vol. 274, pp. 2057-2059.	eterozygosity in Normal Tissue Adjacent to Breast Carcinomas,"		
	C18	Deuter et al., (1995) "A Method for Preparation Vol. 23, No. 18, pp. 3800-3801.	on of Fecal DNA Suitable for PCR," Nucleic Acids Research,		
	C19 Dib et al., (March 14, 1996) "A Comprehensive Genetic Map of the Human Genome Based on 5,264 Microsatellites," Nature Vol. 380, pp. 152-154.				
	C20 Duffy M.J., (1995) "Can Molecular Markers Now be Used for Early Diagnosis of Malignancy?" Clin. Vol. 41, No.10, pp. 1410-1413.				
	C21 Eguchi et al., (April 15, 1996) "Mutations of the p53 Gene in the Stool of Patients with Resectable Colorec Cancer," Cancer Supplement, Vol. 77, No. 8, pp. 1707-1710.				
	C22 Enari et al., (January 1, 1998) "A Caspase-Activated DNase that Degrades DNA During Apoptosis, and it Inhibitor ICAD," Nature, Vol. 391, pp. 43-50.				
	C23	Fearon, E.R., (1995) "16 Molecular Abnormalities in Colon and Rectal Cancer," The Molecular Basis of Cancer, pp. 340-357.			
	C24	Grossman et al. (1988), "Colonoscopic Screening of persons With Suspected Risk Factors for Colon Cancer"  Gastroenterology 94:395-400.			
	C25	Gyllensten U. B., Allen M., (1995) "Sequencing of In Vitro Amplified DNA," Recombinant DNA Methodology II, (Wu, ed.), pp. 565-578.			
	C26	Hasegawa et al., (1995) "Detection of K-ras M Colorectal Tumors by Mutant-Allele-Specific	Intuitions in DNAs Isolated From Feces of Patients with Amplification (MASA)," Oncogene, Vol. 10, pp. 1441-1445.		
	C27	Hoang et al. (1997) "BAT-26, an Indicator of Lines" Cancer Research 57:300-303.	the Replication Error Phenotype in Cancers and Colorectal Cell		
	C28	Honchel et al., (1995) "Genomic Instability in	Neoplasia," Seminars in Cell Biology, Vol. 6, pp. 45-52.		
	C29	Hoss et al., (September 17, 1992) "Excrement	Analysis by PCR" Scientific Correspondence pp. 199.		
	C30	Iino et al. (1999) "DNA Microsatellite Instabil Polyps: a Mild Mutator Pathway for Colorecta	lity in Hyperplastic Polyps, Serrated Adenomas, and Mixed 1 Cancer?" Journal of Clinical Pathology 52:5-9.		
	C31	Iniesta et al. (1998) "Genetic Abnormalities and Microsatellite Instability in Colorectal Cancer" Cancer <u>Detection and Prevention</u> 22:383-395.			

EXAMINER	DATE CONSIDERED

Ishimaru et al. (1995) "Microsatellite Instability in Primary and Metastatic Colorectal Cancers" International

C32

Journal of Cancer 64:153-157.

#### ATTORNEY DOCKET NO.: EXT-026 **FORM PTO - 1449** APPLICANT(S): Lapidus et al. INFORMATION INSCLOSURE STATEMENT SERIAL NO.: 09/545,162 JUH 0 9 2003 FILING DATE: April 7, 2000 **GROUP: 1634** OTHER ART, JOURNAL ARTICLES, ETC. COLUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) EXAM. INIT. C33 Jarvinen et al. (1995) "Screening Reduces Colorectal Cancer Rate in Families With Hereditary Nonpolyposis Colorectal Cancer" Gastroenterology 108:1405-1411. C34 Jernvall et al. (1999) "Microsatellite Instability: Impact on Cancer Progression in Proximal and Distal Colorectal Cancers" European Journal of Cancer 35:197-201. C35 Jessup J.M. and G.E. Gallick, (September/October 1992) "The Biology of Colorectal Carcinoma," Current Problems in Cancer, pp. 263-328. C36 Jonsson et al., (January 1995) "From Mutation Mapping to Phenotype Cloning," Proc. Natl. Acad. Sci., Vol. 92, pp. 83-85. Kim et al. (1998) "Microsatellite Instability in Young Patients With Colorectal Cancer" Pathology C37 International 48:586-594. C38 Konishi et al. (1996) "Molecular Nature of Colon Tumors in Hereditary Nonpolyposis Colon Cancer, Familial Polyposis, and Sporadic Colon Cancer" Gastroenterology 111:307-317. C39 Lamberti et al. (1999) "Microsatellite Instability - a Useful Diagnostic Tool to Select Patients at High Risk for Hereditary Non-Polyposis Colorectal Cancer: A Study in Different Groups of Patients With Colorectal Cancer" Gut 44:839-843. Lengauer et al., (December 17, 1998) "Genetic Instabilities in Human Cancers," Nature, Vol. 396, C40 pp. 643-649. Leong et al., (1993) "Detection of MYCN Gene Amplification and Deletions of Chromosome 1p in C41 Neuroblastoma by In Situ Hybridization Using Routine Histologic Sections," Laboratory Investigations, Vol. 69, No. 1, pp. 43-50. C42 Lin et al. (1998) "Colorectal and Extracolonic Cancer Variations in MLH1/MSH2 Hereditary Nonpolyposis Colorectal Cancer Kindreds and the General Population" Diseases of the Colon & Rectum 41:428-433. C43 Litia et al., (1992) "Simultaneous Detection of Two Cystic Fibrosis Alleles Using Dual-Label Time-Resolved Fluorometry," Molecular and Cellular Probes, Vol. 6, pp. 505-512. C44 Lleonart et al. (1998) "Microsatellite Instability and p53 Mutations in Sporadic Right and Left Colon Carcinoma" American Cancer Society 83:889-895. C45 Loktionov A. and I. K. O'Neill, (1995) "Early Detection of Cancer-Associated Gene Alterations in DNA Isolated from Rat Feces During Intestinal Tumor Induction with 1,2-Dimethylhydrazine," International Journal of Oncology, Vol. 6, pp. 437-445. C46 Loktionov et al., (February, 1998) "Quantitation of DNA from Exfoliated Colonocytes Isolated from Human Stool Surface as a Novel Noninvasive Screening Test for Colorectal Cancer," Clinical Cancer Research, Vol. 4, pp. 337-341.

EXAMINER	DATE CONSIDERED

#### ATTORNEY DOCKET NO.: EXT-026 **FORM PTO - 1449** INFORMATION DISCLOSURE STATEMENT APPLICANT(S): Lapidus et al. SERIAL NO.: 09/545,162 **GROUP: 1634** FILING DATE: April 7, 2000 OTHER ART, JOURNAL ARTICLES, ETC. R DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) EXAM & TRAC INIT. Mao L. et al., (February 2, 1996) "Molecular Detection of Primary Bladder Cancer by Microsatellite C47 Analysis," Science, Vol. 271, pp. 659-662. Myers, R.M., (February 12, 1993) "The Pluses of Subtraction," Science, Vol. 259, pp. 942-943. C48 Naber S. P., (December 1, 1994) "Molecular Pathology -- Detection of Neoplasia," New England Journal of C49 Medicine, Vol. 331, No. 22, pp. 1508-1510. Nollau et al., (May 1996) "Isolation of DNA from Stool and Bodily Fluids for PCR Amplification," C50 BioTechniques, Vol. 20, No. 5, pp. 784-788. Nollau et al., (1996) "Detection of K-ras Mutations in Stools of Patients with Colorectal Cancer by Mutant-C51 Enriched PCR," Int. J. Cancer, Vol. 66, pp. 332-336. Orlow I., et al., (October 18, 1995) "Deletion of the p16 and p15 Genes in Human Bladder Tumors Journal of C52 the National Cancer Institute, ," Vol. 87, No. 20, pp. 1524-1529. Orou, et al., (1995) "Allele-Specific Competitive Blocker PCR: A One-Step Method With Applicability to C53 Pool Screening" Human Mutation Vol. 6, 163-169. Park et al. (1999) "Gene-Environment Interaction in Hereditary Nonpolyposis Colorectal Cancer with Implications for Diagnosis and Genetic Testing" International Journal of Cancer 82:516-519. Peltomaki et al. (1997) "Mutations Predisposing to Hereditary Nonpolyposis Colorectal Cancer: Database and C55 Results of a Collaborative Study" Gastroenterology 113:1146-1158. Pharmacia, (1998) BioDirectory, pp. 104-109. C56 Pharmacia, (1991/1992) Molecular and Cell Biology Catalogue, pp. 8.3-8.6. C57 Piao et al., (September 1997) "Relationship between Loss of Heterozygosity of Tumor Suppressor Genes and C58 Histologic Differentiation in Hepatocellular Carcinoma," Cancer, Vol. 80, No. 5, pp. 865-872. Ponz de Leon et al. (1998) "Frequency and Type of Colorectal Tumors in Asymptomatic High -Risk C59 Individuals in Families with Hereditary Nonpolyposis Colorectal Cancer" Cancer Epidemiology, Biomarkers & Prevention 7:639-641. Ponz de Leon et al. (1999) "Hereditary Colorectal Cancer in the General Population: From Cancer Registration C60 to Molecular Diagnosis" Gut 45:32-38. Pyatt et al. (1999) "Polymorphic Variation at the BAT-25 and BAT-26 Loci in Individuals of African Origin" C61 American Journal of Pathology 155:349-353. Raff, M., (November 12, 1998) "Cell Suicide for Beginners," Nature, Vol. 396, pp. 119-122. C62 C63 Rashid et al. (1999) "Genetic Epidemiology of Mutated K-ras Proto-Oncogene, Altered Suppressor Genes, and Microsatellite Instability in Colorectal Adenomas" Gut 44:826-833.

	EXAMINER	DATE CONSIDERED
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#### ATTORNEY DOCKET NO.: EXT-026 **FORM PTO - 1449** APPLICANT(S): Lapidus et al. INFORMATION DISCLOSURE STATEMENT SERIAL NO.: 09/545,162 FILING DATE: April 7, 2000 **GROUP: 1634** 0 9 2003 OTHER ART, JOURNAL ARTICLES, ETC. OTHER SOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) EXAM. INIT. Ravelingien et al., (1995) "Contribution of Molecular Oncology in the Detection of Colorectal Carcinomas," C64 Acta Gastro-Enterologica Belgica, Vol. 58, pp. 270-273. Riegler et al. (1999) "Prevalence of HNPCC in a Series of Consecutive Patients on the First Endoscopic C65 Diagnosis of Colorectal Cancer: A Multicenter Study" Endoscopy 31:337-341. Rhyu M. S., (March 6, 1996) "Molecular Mechanisms Underlying Hereditary Nonpolyposis Colorectal C66 Carcinoma," Journal of the National Cancer Institute, Vol. 88, No. 5, pp. 240-251. Ridanpaa et al., (1995) "Detection of Loss of Heterozygosity in the p53 Tumor Suppressor Gene Using a PCR-C67 based Assay," Path. Res. Pract., Vol. 191, pp. 399-402. Rodriguez-Bigas et al. (1997) "A National Cancer Institute Workshop on Hereditary Nonpolyposis Colorectal C68 Cancer Syndrome: Meeting Highlights and Bethesda Guidelines" Journal of the National Cancer Institute 89:1758-1762. Salahshor et al. (1999) "Microsatellite Instability in Sporadic Colorectal Cancer is Not an Independent C69 Prognostic Factor" British Journal of Cancer 81:190-193. Samowitz et al. (1995) "Microsatellite Instability in Human Colonic Cancer Is Not a Useful Clinical Indicator C70 of Familial Colorectal Cancer" Gastroenterology 109:1765-1771. Samowitz et al. (1997) "Microsatellite Instability in Colorectal Adenomas" Gastroenterology 112:1515-1519. C71 C72 Samowitz et al. (1999) "BAT-26 and BAT-40 Instability in Colorectal Adenomas and Carcinomas and Germline Polymorphisms" American Journal of Pathology 154:1637-1641. Sanger et al., (December 1977) "DNA Sequencing with Chain-Terminating Inhibitors" Proc. Natl. Acad. Sci. C73 USA, Vol. 74, No. 12, pp. 5463-5467. C74 Santagati et al., (1997) "Quantitation of Low Abundance mRNAs in Glial Cells Using Different Polymerase chain Reaction (PCR)-Based Methods," Elsevier Science - Brain Research Protocols, pp. 217-223. Segel I., (1976), "Double Label Analysis," Biochemical Calculations, 2d ed., pp. 373-376. C75 Sidransky, et al., (April 3, 1992) "Identification of ras Oncogene Mutations in the Stool of Patients with C76 Curable Colorectal Tumors," Science, Vol. 256, pp. 102-105. C77 Smith-Ravin et al., (1995) "Detection of c-Ki-ras Mutations in Faecal Samples from Sporadic Colorectal Cancer Patients," Gut, Vol. 36, pp. 81-86. Syngal et al. (1998) "Benefits of Colonoscopic Surveillance and Prophylactic Colectomy in Patients With C78 Hereditary Nonpolyposis Colorectal Cancer Mutations" Annals of Internal Medicine 129:787-796. Syngal et al. (1999) "Interpretation of Genetic Test Results for Hereditary Nonpolyposis Colorectal Cancer" C79 JAMA 282:247.

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EXAMINER	DATE CONSIDERED
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FORM PTO - 1449			ATTORNEY DOCKET NO.: EXT-026		
JUN 0 9 2003			APPLICANT(S): Lapidus <i>et al.</i> SERIAL NO.: 09/545,162		
					FILING DATE: April 7, 2000 GROUP: 1634
				To The	OTHER ART, JOURN
EXAM. OTHER DOCUMENTS: (Including Author, Tit					
	C80	Takeda et al., (1993) "Detection of K-ras Mut (MASA)," <u>Human Mutation</u> , Vol. 2, pp. 112-1	ation in Sputum by Mutant-Allele-Specific Amplification		
	C81	Thibodeau <i>et al.</i> , (May 7, 1993) "Microsatellit Vol. 260, pp. 816-819.	e Instability in Cancer of the Proximal Colon," Science,		
C82 Vasen et al. (1993) "Surveillance in Hereditary Nonpolyposis Colorectal Cancer: An International Coop Study of 165 Families" <u>Diseases of the Colon &amp; Rectum</u> ) 36:1-4.			y Nonpolyposis Colorectal Cancer: An International Cooperative & Rectum) 36:1-4.		
C83 Vasen et al. (1998) "A Cost-Effectiveness Analysis of Colorectal Screening of Colorectal Carcinoma Gene Carriers" American Cancer Society 82:1632-163			alysis of Colorectal Screening of Hereditary Nonpolyposis on Cancer Society 82:1632-1637.		
C84 Vasen et al. (1999) "New Clinical Criteria for Heredital Syndrome) Proposed by the International Collaborative			Hereditary Nonpolyposis Colorectal Cancer (HNPCC, Lynch aborative Group on HNPCC" Gastroenterology 116:1453-1456.		
C85 Villa et al., (May 1996) "Identification of Subjects at Risk for Colorectal Carcinoma Through a Test E K-ras Determination in the Stool," <u>Gastroenterology</u> , Vol. 110, No. 5, pp. 1346-1353.			ects at Risk for Colorectal Carcinoma Through a Test Based on ology, Vol. 110, No. 5, pp. 1346-1353.		
	C86				
	C87	Wallace et al., (1979) "Hybridization of Synthetic Oligodeoxyribonucleotides to Φχ 174 DNA: the Effect of Single Base Pair Mismatch," Nucleic Acids Research, Vol. 6, No. 11, pp. 3543-3557.			
	C88	Walsh et al., (February 6, 1992) "Preferential PCR Amplification of Alleles: Mechanisms and Solutions," PC Methods and Applications, pp. 241-250.			
	C89	Wang et al., (May 15, 1998) "Large-Scale Iden Olymorphisms in the Human Genome," <u>Science</u>	ntification, Mapping, and Genotyping of Single-Nucleotide e, Vol. 280, pp. 1077-1082.		
	C90	Watson <i>et al.</i> , "Isolation of Differentiality Expr Brief XP 000576043, pp. 4598-4602.	ressed Sequence Tags from Human Breast Cancer," Advances in		
	C91	Wijnen et al. (1999) "Familial Endometrial Car Genetics 23:142-144.	ncer in Female Carriers of MSH6 Germline Mutations" Nature		
	C92	Young G.P., and B.H. Demediu, (1992) "The Cancers" Current Opinion in Oncology, Vol. 4	Genetics, Epidemiology, and Early Detection of Gastrointestinal, pp. 728-735.		
	C93	Zhou et al. (1997) "Allelic Profiles of Mononu Colorectal Tumors With and Without Replicati	cleotide Repeat Microsatellites in Control Individuals and in on Errors" Oncogene 15:1713-1718.		
	C94	Zhou et al. (1998) "Determination of the Replic Requirement for Matching Normal DNA by An Chromosomes & Cancer 21:101-107.	cation Error Phenotype in Human Tumors Without the allysis of Mononucleotide Repeat Microsatellites" Genes.		

EXAMINER	DATE CONCIDEDED
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#### ATTORNEY DOCKET NO.: EXT-026 **FORM PTO - 1449** APPLICANT(S): Lapidus et al. INFORMATION DISCIPOSURE STATEMENT SERIAL NO.: 09/545,162 FILING DATE: April 7, 2000 **GROUP: 1634** JUN 0 9 2003 🕏 OTHER ART, JOURNAL ARTICLES, ETC. ON LOOP COMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) EXAM. INIT. Allen et al. (1997), "Morphological and biochemical characterization and analysis of apoptosis." J. Pharm. & C95 Toxicol. Methods, Vol. 37, No. 4, pp. 215-28. Ambrosini et al. "A novel anti-apoptosis gene, survivin, expressed in cancer and lymphoma" Nature Medicine, C96 Vol. 3, No. 8, pp. 917-921, August 1997. Anker et al., (1999), "Detection of Circulating Tumour DNA in the Blood (plasma/serum) of Cancer Patients," C97 Cancer and Metastasis Reviews, Vol. 18, pp. 65-73. Arber et al. "A K-ras Oncogene Increases Resistance to Sulindac-Induced Apoptosis in Rat Enterocytes," C98 Gastroenterology, Vol. 113, No. 6, pp. 1892-1900, December 1997. Azhikina et al. (1996), "Factors Affecting the Priming Efficiency of Short Contiguous Oligonucleotide Strings C99 in the Primer Walking Strategy of DNA Sequencing," DNA Sequence 6:211-16. Barry et al. "Identification of Deoxyribonuclease II as an Endonucleas Involved in Apoptosis," Archives of C100 Biochemistry and Biophysics, Vol. 300, No. 1, pp. 440-448, January 1993. Bernstein et al. "A Bile Acid-induced Apoptosis Assay for Colon-Cancer Risk and Associated Quality Control Studies," Cancer Research, Vol. 59, pp. 2353-2357, May 15, 1999. Boom et al., (March 1990) "Rapid and Simple Method for Purification of Nucleic Acids" J. Clin. Microbiol., C102 Vol. 28, No. 3, pp. 495-503. Croitoru et al. "Reduce, Reuse, and Recycle: Shedding Light on Shedding Cells," Gastroenterology, Vol. 105, C103 pp. 1243-1246, October 1993. Cawkwell et al. (1994), "Frequency of allele loss of DCC, p53, RB1, WT1, NF1, NM23 and APC/MCC in colorectal cancer assayed by fluorescent multiplex polymerase chain reaction." Brit. J. Can., Vol. 70, No. 5, C104 pp. 813-818. Chen et al., (July 15, 1996), "Detection of Single-Base Mutations by a Competitive Mobility Shift Assay," C105 Analytical Biochemistry, US, Academic, Press, Vol. 239, No. 1, pp. 61-69. Coombs et al., (May 21, 1996) "A Rapid, Simple, and User-Friendly Method for DNA Extraction from Clinical Stool Samples," ASM 1996 General Meeting, New Orleans, LA. C106 Dennin, (1979), "DNA of Free and Complexed Origin in Human Plasma: Concentration and Length C107 Distribution," Klin. Wochenschr, Vol. 57, pp. 451-456. Depraetere, "'Eat me' Signals of apoptotic bodies," Nature Cell Biology, Vol. 2, pg. E104, June 2000. C108 Ditkoff et al. (1996), "Detection of circulating thyroid cells in peripheral blood." Surgery Vol. 120, No. 6, C109 pp. 959-65. Eads et al., (1999) "CpG Island Hypermethylation in Human Colorectal Tumors Is Not Associated with DNA Methyltransferase Overexpression." Cancer Research, Vol. 59, No. 10, pp. 2302-2306. C110

DATE CONSIDERED

**EXAMINER** 

#### ATTORNEY DOCKET NO.: EXT-026 **FORM PTO - 1449** APPLICANT(S): Lapidus et al. INFORMATION OIF OLOS URE STATEMENT SERIAL NO.: 09/545,162 JUN 0 9 2003 FILING DATE: April 7, 2000 **GROUP: 1634** OTHER ART, JOURNAL ARTICLES, ETC. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) EXAM. INIT. Echeverria et al., (September 1985) "DNA Hybridization in the Diagnosis of Bacterial Diarrhea," Clinics in C111 Laboratory Medicine, Vol. 5, No. 3, September 1985, pp. 447-462. Emlen et al., (1984), "Effect of DNA Size and Strandedness on the in vivo Clearance and Organ Localization C112 of DNA," Clin. exp. Immunol., Vol. 56, pp. 185-192. Finkel "Does Cancer Therapy Trigger Cell Suicide?," Science, Vol. 286, pp.2256-2258, December 17, 1999. C113 Fournie et al., (1995), "Plasma DNA as a Marker of Cancerous Cell Death. Investigations in Patients Suffering C114 from Lung Cancer and in Nude Mice Bearing Human Tumours," Cancer Letters, Vol. 91, pp. 221-227. Garewal et al. "Reduced Bile Acid-induced Apoptosis in 'Normal' Colorectal Mucosa: A Potential Biological C115 Marker for Cancer Risk," Cancer Research, Vol. 56, pp. 1480-1483, April 1, 1996. Giacona, et al. (1998), "Cell-free DNA in Human Blood plasma: Length Measurements in Patients with C116 Pancreatic Cancer and Healthy Controls," Pancreas, Vol. 17, No. 1, pp. 89-97. Halim, "Apoptosis: Orderly Dismantling," The Scientist, pg. 19, February 7, 2000. C117 Hall et al. "Regulation of cell number in the mammalian gastrointestinal tract: the importance of apoptosis," C118 Journal of Cell Science, Vol. 107, pp. 3569-3577, 1994. Hetts, "To Die or Not to Die, An Overview of Apoptosis and Its Role in Disease," JAMA, Vol. 279, No. 4, C119 pp. 300-307, January 28, 1998. Hibi et al., (April 1998), "Molecular Detection of Genetic Alterations in the Serum of Colorectal Cancer C120 Patients," Cancer Research, Vol. 58, pp. 1405-1407. Hitchcock, "Actin- Deoxyribonuclease I Interaction," The Journal of Biochemical Chemistry, Vol. 255, C121 No. 12, pp. 5668-5673, 1980. Hunsaker, et al. (1989), "Use of Reversible Target Capture to Detect Subattomole Quantities of Target C122 Nonradioleotopically in Crude Specimens in One Hour," Abstracts of the 89th Meeting of the American Society for Microbiology, D-169, pg. 110. Ito et al., (1999), "Profile of Circulating Levels of Interleukin-1 Receptor Antagonist and Interleukin-6 in Colorectal Cancer Patients," Scand. J. Gastroenterol., Vol. 11, pp. 1139-1143. Iwanaga et al. "A Novel Mechanism for Disposing of Effete Epithelial Cells in the Small Intestine of Guinea C124 Pigs," Gastroenterology, Vol. 105, No. 4, pp. 1089-1097, 1993. Kataoka et al. "Association of high molecular weight DNA fragmentation with apoptotic or non-apoptotic cell C125 death induced by calcium ionophore" FEBS Letters, Vol. 364, pp. 264-267, 1995. Kawasaki et al. "Inhibition of Apoptosis by Survivin Predicts Shorter Survival Rates in Colorectal Cancer," C126

EXAMINER	DATE CONSIDERED

Cancer Research, Vol. 58, pp. 5071-5074, November 15, 1998.

FORM	PTO - 1	449	ATTORNEY DOCKET NO.: EXT-026
INFORMATION DISPLOSURE STATEMENT		NO SELOSURE STATEMENT	APPLICANT(S): Lapidus et al.
		O We go	SERIAL NO.: 09/545,162
		JUN 0 9 2003 2	FILING DATE: April 7, 2000 GROUP: 1634
	- 1	72 1 13-1	NAL ARTICLES, ETC.
EXAM. INIT.		CUMENTS: (Including Author, Ti	tle, Date, Relevant Pages, Place of Publication)
	C127		se I (DNase I) Polymorphism: Pattern Similarities among and Pancreas," Am. J. Hum. Genet., Vol. 47, pp. 121-126, 1990.
	C128	Komano et al. "Homeostatic regulation of int Sci. USA 92, Vol. 92, pp. 6147-6151, June 19	estinal epithelia by intraepithelial γδ T cells" <i>Proc. Natl. Acad.</i> 195.
	C129 Lefrere et al., (October 1998) "Screening Blood Donations for Viral Genomes: Multicenter Study of Real- Time Simulation Using Pooled Samples on the Model of HCV RNA Detection," <i>Transfusion</i> , Vol. 38, pp. 915-923.		
<ul> <li>C130 Leon et al., (March 1977), "Free DNA in the Serum of Cancer Patients and the Effect of Therapy," Cancer Research, Vol. 37, pp. 646-650.</li> <li>C131 Li et al., (August 1996) "Rapid Detection of Mycobacterium Avium in Stool Samples from AIDS Patients Immunomagnetic PCR," J. Clin. Microbiol., Vol. 34, No. 8, pp. 1903-1907.</li> <li>C132 Lipkin, "Biomarkers of Increased Susceptibility to Gastrointestinal Cancer: New Application to Studies of Cancer Prevention in Human Subjects," Cancer Research, Vol. 48, pp. 235-245, January 15, 1998.</li> <li>C133 Maebo, (1990), "Plasma DNA Level as a Tumor Marker in Primary Lung Cancer," Japanese; English absattached.</li> </ul>		Serum of Cancer Patients and the Effect of Therapy," Cancer	
		nor Marker in Primary Lung Cancer," Japanese; English abstract	
	C134	C134 Mannherz et al. "A Specific 1:1 G-Actin: DNAase I Complex Formed by the Action of DNAase I on F-Actin," FEBS Letters, Vol. 60, No. 1, pp. 34-38, December 1975.  C135 Mannherz et al. "The Interaction of Bovine Pancreatic Deoxyribonuclease I and Skeletal Muscle Actin," Eur. J. Biochem, Vol. 104, pp. 367-379, 1980.	
	C135		
	C136 Metspalu A., "Arrayed Primer Extension (APEX) for Mutation Detection Using Gene-Specific DNA Chips'  European Society of Human Genetics, Vol. 6, No. Sup 1, 1998, page PL36 XP000892253 Abstract.		
	C137	Morandi et al., (June 1998) "Detection of HI and HIV-2," J. of Clinical Microbiology, Vo	V Type 1 RNA in Pools of Sera Negative for Antibodies to HIV-1 l. 36, No. 6, pp. 1534-1538.
	C138	Morrissey et al., (May 14-18, 1989) "Novel Specimens," American Society for Microbiol	Hybridization Technique with Subattomole Sensitivity in logy, 89 <sup>th</sup> Annual Meeting, Abstract D-168, pg. 110.
	C139	Morrissey, et al., (September 1989) "Nucleic Probes," Analytical Biochemistry, Vol. 181,	c Acid Hybridization Assays Employing dA-Tailed Capture No. 2, pp. 345-359.
	C140	Morrissey, D. and Collins, M., (June 1989) 'Probes: Single Capture Methods," Mol. And	Nucleic Acid Hybridization Assays Employing dA-Tailed Capture a Cell. Probes, Vol. 3, No. 2, pp. 189-207.
	C141	Mulcahy et al. (1998), "A prospective study Clin. Cancer Res., Vol. 4, pp. 271-75.	of K-ras mutations in the plasma of pancreatic cancer patients,"

EXAMINER	DATE CONSIDERED

FORM PTO - 1449		1449	ATTORNEY DOCKET NO.: EXT-026
INFORMACION DESCLOSURE STATEMENT		N DESCLOSURE STATEMENT	APPLICANT(S): Lapidus et al.
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	Ve IR	OTHER ART, JOURN	IAL ARTICLES, ETC.
EXAM. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication) INIT.		tle, Date, Relevant Pages, Place of Publication)	
	C142		oxigenic Escherichia coli after Polymerase Chain Reaction merase," Journal of Clinical Microbiology, Vol. 27, No. 2,
	C143	Paabo et al., (1988) "Mitochondrial DNA Seq. Vol. 16, No. 20, pp. 9775-9787.	uences from a 7000-year old Brain," Nucleic Acids Research,
	C144	Pacek et al., (May 1993)"Determination of Allele Frequencies at Loci with Length Polymorphism by Quantitative Analysis of DNA Amplified from Pooled Samples," PCR Methods and Applications, Vol. 2, No. 4, pp. 313-317.	
	C145	Park et al. "Detergent and Enzyme Treatment of Apoptotic Cells for Observation of DNA Fragmentation,"  BioTechniques, Vol. 24, No. 4, pp. 558-559, 1998.	
	C146	Payne et al. "Role of Apoptosis in Biology and Pathology: Resistance to Apoptosis in Colon Carcinogenesis,"  Ultrastructural Pathology, Vol. 19, pp. 221-248, 1995.	
	C147 Peitsch et al. "Characterization of the endogenous deoxyribonuclease involved in nuclear DNA degradation during apoptosis (programmed cell death)," The EMBO Journal, Vol. 12, No. 1, pp. 371-377, 1993.		
	C148	Peitsch et al. "Functional characterisation of serum DNase I in MRI," Biochemical and Biophysical Research Communications, Vol. 186, No. 2, pp. 739-745, July 31, 1992.	
	C149	Peitsch et al. "The apoptosis endonucleases: cleaning up after cell death?," Trends in Cell Biology, Vol. 4, pp. 37-41, February 4, 1994.	
	C150	Polzar et al. "Distribution of deoxyribonuclease I in rat tissues and its correlation to cellular turnover and apoptosis (programmed cell death)," European Journal of Cell Biology, Vol. 64, pp. 200-210, 1994.	
	C151	Polzar et al. "Overexpression of deoxyribonuclease I (DNase I) transfected into COS-cells: its distribution during apoptotic cell death," European Journal of Cell Biology, Vol. 62, pp. 397-405, 1993.	
	C152 Raptis et al., (December 1980), "Quantitation and Characterization of Plasma DNA in Normals and Patients with Systemic Lupus Erythematosus," J. Clin. Invest., Vol. 66, pp. 1391-1399.		
	C153	C153 Rinaldy et al. (1988), "Gene Cloning Using cDNA Libraries in a Differential Competition Hybridization Strategy: Application to Cloning XP-A Related Genes," DNA Vol. 7, No. 8, pp. 563-70.	
	C154	Ruzicka et al., (1992) "Apolipoprotein Allele J. of Lipid Research, Vol. 33, pp. 1563-1567.	Specific PCR: Large-Scale Screening of Pooled Blood Samples,"
	C155	Saitoh <i>et al.</i> "Analysis of Bel-2, Bax and Surv Vol. 15, pp. 137-141, 1999.	vivin genes in uterine cancer," International Journal of Oncology,
	C156	Sales et al., (July 31, 1999), "Blood Dissemin Rectosigmoid Cancer," The Lancet, Vol. 354,	ation of Colonic Epithelial Cells During No-touch Surgery for pg. 392.

EXAMINER DATE CONSIDERED
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FORM PTO - 1449		1449	ATTORNEY DOCKET NO.: EXT-026
INFORMATION DISCLOSURE STATEMENT		ON DISCLOSURE STATEMENT	APPLICANT(S): Lapidus et al.
1 1	JUN 0 9 2003		SERIAL NO.: 09/545,162
1			FILING DATE: April 7, 2000 GROUP: 1634
	J. P.	OTHER ART, JOURN	NAL ARTICLES, ETC.
EXAM. INIT.	EXAM. OTHER DOCUMENTS: (Including Author, Titl		tle, Date, Relevant Pages, Place of Publication)
	C157	Samiotaki et al. (1994), "Dual-Color Detection Genomics 20:238-42.	n of DNA Sequence Variants by Ligase-Mediated Analysis,"
	C158 Schmitt et al. (1998), "Bax-alpha promotes an activation of caspase 3-like cysteine proteases & Diff., Vol. 5, No. 6, pp. 506-16.		poptosis induced by cancer chemotherapy and accelerates the in p53 double mutant B lymphoma Namalwa cells," Cell Death
	<ul> <li>C159 Sen "Programmed Cell Death: Concept, Mechanism and Control," Biol. Rev., Vol. 67, pp. 287-319, 1992.</li> <li>C160 Shapiro et al., (June 1, 1983), "Determination of Circulating DNA Levels in Patients with Benign or Malign Gastrointestinal Disease," Cancer, Vol. 51, No. 11, pp. 2116-2120.</li> <li>C161 Shaw et al., (1998) "Allele Frequency Distribution in Pooled DNA Samples, Applications to Mapping Complex Disease Genes," Genome Research, Vol. 8, pp. 111-123.</li> </ul>		anism and Control," Biol. Rev., Vol. 67, pp. 287-319, 1992.
			of Circulating DNA Levels in Patients with Benian or Malianant
			ution in Pooled DNA Samples, Applications to Mapping Vol. 8, pp. 111-123.
<ul> <li>C162 Sidransky, D. (1997) "Nucleic acid-based methods for the detection of cancer," Science, Vol. 278, No. pp. 1054-1058.</li> <li>C163 Skoletsky et al. (1998) "High frequency of detecting amplifiable DNA in stools of apparently normal individuals," Gastroenterology, Vol. 114, No. 4, pg. A681.</li> </ul>		hods for the detection of cancer," Science, Vol. 278, No. 5340,	
		ecting amplifiable DNA in stools of apparently normal 4, pg. A681.	
	C164	Human Colonic Crypt Cell" Gastroenterology, Vol. 110, No. 6, pp. 1776-1784, June 1996.  Stroun et al., (1987), "Isolation and Characterization of DNA from the Plasma of Cancer Patients," Eur. J. Cancer Clin. Oncol., Vol. 23, No. 6, pp. 707-712.	
	C165		
	C166		
	C167	Tsujitani et al. "Apoptotic Cell Death and Its F Cancer Supplement, Vol. 77, No. 8, pp. 1711-	Relationship to Carcinogenesis in Colorectal Carcinoma," 1716, April 15, 1996.
	C168	Vera-Garcia, et al., (May 16-20 1993) "Develor Reproducibly Release Nucleic Acids from Mic Chain Reaction, 93 <sup>rd</sup> General Meeting, Session	opment and Evaluation of an Instrument Designed to croorganisms," American Society for Microbiology: Polymerase 1214, Abstract C-217, pg. 484.
	C169 Vet et al., (1998) "Comparative analysis of p53 mutations in bladder washings and histologic specimens," A J. Clin. Path., Vol. 110, No. 5, pp. 647-652.		3 mutations in bladder washings and histologic specimens," Am.
	C170	Vogelstein et al., (1979) "Preparative and Anal Sci. USA, Vol. 76, No. 2, pp. 615-619.	lytical Purification of DNA from Agarose," Proc. Natl. Acad.
	C171	Wagner et al. "Regulation of Gastric Epithelial of Apoptosis," Gastroenterology, Vol. 113, No.	Cell Growth by Helicobacter pylori: Evidence for a Major Role o. 6, pp. 1836-1847, December 1997.

EXAMINER	
EXAMILIER	DATE CONSIDERED
	J.II CONSIDERED

INFORMATION DISCLOSURE STATEMENT
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ATTORNEY DOCKET NO.: EXT-026

APPLICANT(S): Lapidus et al.

SERIAL NO.: 09/545,162

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GROUP: 1634

	FR	OTHER ART, JOURNAL ARTICLES, ETC.
EXAM. INIT.	EXAM. OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C172	Walsh et al., (1991) "Chelex® 100 as a Medium for Simple Extraction of DNA for PCR-Based Typing from Forensic Material," BioTechniques, Vol. 10, No. 4, pp. 506-513.
	C173	Walton et al., (1997) "A PCR-Based Method for Detecting Rare Genotypes in Large Samples of Individuals," Mol. Ecology, Vol. 6, No. 2, pp. 195-197.
	C174	Zhang et al. "Quantitative determination of apoptotic death in cultured human pancreatic cancer cells by propidium iodide and digitonin," Cancer Letters, Vol. 142, pp. 129-137, 1999.
	C175	Ahlquist et al., "Colorectal Cancer Screening by Detection of Altered Human DNA in Stool: Feasibility Multitarget Assay Panel," Presented at Digestive Disease Week Annual Conference, Orlando, FL, May 19, 1999 (Gastroenterology, 119, pp. 1219-1227 (2000)).
	C176	Ahlquist et al., "Universal Detection of Aerodigestive Cancers by Assay of Nonapoptotic Human DNA in Stool," Presented at Digestive Disease Week Annual Conference, San Diego, CA, May 2000.
	C177	Makristathis et al., "Detection of Helicobacter pylori in Stool Specimens by PCR and Antigen Enzyme Immunoassay," Journal of Clinical Microbiology, Vol. 36, No. 9, pp. 2772-2774, September 1998.

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EXAMINER	DATE CONSIDERED